PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 19 October 1998 (19.10.98)	
International application No. PCT/EP98/00522	**Applicant's or agent's file reference** NO 5804/WO
International filing date (day/month/year) 21 January 1998 (21.01.98)	**Priority date** (day/month/year) 28 February 1997 (28.02.97)
Applicant BOURGUIGNON, Michel	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

02 September 1998 (02.09.98)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Nicola Wolff
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
NO 5804/WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 98/ 00522	21/01/1998	28/02/1997
Applicant		
SOCIETE DES PRODUITS NESTLE S.A. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [ ] **Certain claims were found unsearchable** (see Box I).

2. [ ] **Unity of invention is lacking** (see Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] Transcribed by this Authority

4. With regard to the **title,**
   - [X] the text is approved as submitted by the applicant
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   - [X] the text is approved as submitted by the applicant
   - [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:
   Figure No. 1
   - [X] as suggested by the applicant.
   - [ ] because the applicant failed to suggest a figure.
   - [ ] because this figure better characterizes the invention.
   - [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 98/00522

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61J1/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 696 448 A (MATERIAL ENGINEERING TECHNOLOGY LABORATORY, INC.) 14 February 1996 see column 4, line 11 - column 6, line 11; figures 1-3,6	1-4,8,9, 11,12
X	WO 85 03432 A (TRAVENOL EUROPEAN RESEARCH AND DEVELOPMENT CENTRE) 15 August 1985 see page 9, line 5 - line 20; figures 1-3	1-4,8,9, 11,12
X	WO 95 16490 A (BAXTER INTERNATIONAL INC.) 22 June 1995 see page 14, line 3 - page 19, line 9; figures 1-4	1-4,12

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 May 1998	22/05/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Baert, F

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	DE 39 20 775 A (FRESENIUS AG) 3 January 1991 see column 1, line 11 - line 23 see column 2, line 53 - column 4, line 7; figures -----	1-4, 10-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 98/00522

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 696448 A	14-02-1996	JP 8052196 A	27-02-1996
		US 5662642 A	02-09-1997
WO 8503432 A	15-08-1985	US 4583971 A	22-04-1986
		AU 580584 B	19-01-1989
		AU 3933085 A	27-08-1985
		CA 1234369 A	22-03-1988
		EP 0172836 A	05-03-1986
		JP 3049262 B	29-07-1991
		JP 61501129 T	12-06-1986
WO 9516490 A	22-06-1995	US 5484406 A	16-01-1996
		AU 7732394 A	03-07-1995
		CA 2154764 A	22-06-1995
		EP 0684857 A	06-12-1995
		JP 2736510 B	02-04-1998
		JP 7194710 A	01-08-1995
DE 3920775 A	03-01-1991	NONE	

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
NO 5804/WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP98/00522	21/01/1998	28/02/1997
International Patent Classification (IPC) or national classification and IPC A61J1/20		
Applicant SOCIETE DES PRODUITS NESTLE S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02/09/1998	21.05.99
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. (+49-89) 2399-0 Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Derrien, Y Telephone No. (+49-89) 2399 2622

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP98/00522

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-12 as originally filed

Claims, No.:

1-14 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5-7
	No:	Claims	1-4, 8-9, 10-11
Inventive step (IS)	Yes:	Claims	12-14
	No:	Claims	1-11
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Reference is made to the following documents:

D1: **EP-A-0 696 448**
D2: **WO-A-85 03432**
D3: **DE-A-3920775**
D4: **WO-A-95 16490**

Re Item V

1.1 The subject-matter of the apparatus-claim **1** is not new (Article 33(2) PCT).
The document D1 discloses (Fig.3) an apparatus which is suitable for modifying and feeding a liquid nutritional feeding composition. It comprises a chamber (1, named instillator) which is suitable for receiving a beneficial agent. The chamber has an inlet (7) connectable (i.e. suitable for being connected) to a container (11. named medicator) and an outlet (2) connectable to a feeding means. The apparatus comprises also pumping means associated with the chamber. According to column 5 line 53-column 6 line 4, the pumping means are here considered to be the container (11) and the flexible wall of the chamber (1): nutritional feeding composition can be pressed from the container (11) into the chamber (1) and back to the container (11).

It is to be remarked that the chamber (A) in Fig.1 of D3 anticipates also the claimed apparatus. It is in particular fitted with an inlet (11) connectable to a container (B) containing the nutritional feeding composition and with an outlet (4) which could be connected to a feeding means. Both containers (A) and (B) are flexible and are used as pumping means (Column 3 lines 58-68).

1.2 The dependent claims **2-9** concern features which are well known in the art or which are adaptations falling within the scope of customary practice followed by the skilled person, such that these claims do not appear to contain any additional features which are new and involve an inventive step as required by Article 33 PCT, when combined with the subject-matter of any claim to which they refer.

In particular, the additional feature of claim **2** is also known from D1.
For claim **3**: A chamber having an inlet and an outlet simply connectable and provided with a flexible wall capable of being squeezed and released for pumping

is generally known and thus not new: it is anticipated for example by commonly known manual laboratory pumps.
As to claim 4, the chamber (A) of D3 contains medicaments.
Claims **5-7** relate to the obvious selection of particular values of time or of composition.
As to claims **8-9**: Hollow spikes are the usual means to create a fluid path between medical devices (see spike 4 in D1 or spike 55 in Fig.3 of D2).

2. The subject-matter of claims **10** and **11** lacks novelty (Article 33(2) PCT). It is known to use devices as disclosed in D1 for modifying and supplying of liquid nutritional feeding composition (see D1 column 5 line 53 to column 6 line 11).

3.1 In view of the available prior art, the independent method-claim **12** meets the requirements of the PCT in respect of novelty, inventive step and industrial application (Article 33 (2), (3) and (4) PCT) for the following reasons:
The documents D1, D2, D3 and D4 reflecting the prior art show devices wherein a first (intermediate) container containing diluent or instilliator is connected at one end to a second container filled with medicator or drug and at the other end to feeding means (see **D1**: col.5 li.57-col.6 li.11; **D2**: p.9 li.18-20; **D3**: col.3 li.58-col.4 li.7; **D4**: p.14 li.23-29). In use, the flexible wall of the first container is squeezed so that the diluent is pressed into the second container. After the drug has been dissolved or mixed with the diluent, the second container is in turn squeezed so that the resultant solution is transferred back into the first container and flows through the first container into the feeding means.

According to the method proposed by the present invention, the beneficial agent is contained by the first (and not in the second) container and the liquid nutritional feeding composition (i.e. the diluent) is placed in the second container.
This intermediate position of the beneficial agent goes against the usual arrangement taught in all documents cited in the search report and is therefore new and not obvious.

3.2 The dependent claims **13-14** relate to preferred embodiments of the subject-matter of claim 12 and also meet the requirements of Article 33 (2), (3) and (4) PCT.

Re Item VII

1. If the Applicant is aware of a document reflecting the prior art which is described on page 2 lines 9-14, then the document should be identified in the description (Rule 5.1 (a) (ii) PCT).

2. The features of claims **1-14** are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Vis-à-vis the available prior art, it appears that a new independent apparatus-claim directed to the whole system, i.e. to a chamber having an inlet connected to a container containing the nutritional feeding composition and an outlet connected to a feeding means, and combined with the additional features of claim 3 (one flexible wall capable of being squeezed and released for pumping) or those of claim 4 (the chamber comprising at least one beneficial agent...) would have met the requirements of the PCT in respect of novelty and inventive step.
With such a claim, any objection concerning the clarity of claims 9 and 12 would be obsolete. At present, claims 9 and 12 are unclear (Article 6 PCT), because no feeding means is explicitly defined in claim 1 (the chamber is only connectable to a feeding means).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
NO 5804/WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 98/ 00522	21/01/1998	28/02/1997
Applicant		
SOCIETE DES PRODUITS NESTLE S.A. et al.		

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This International Search Report consists of a total of 3 sheets.

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1. [ ] **Certain claims were found unsearchable** (see Box I).

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   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] Transcribed by this Authority

4. With regard to the **title,**
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   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
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6. The figure of the **drawings** to be published with the abstract is:
   Figure No. 1
   - [X] as suggested by the applicant.
   - [ ] because the applicant failed to suggest a figure.
   - [ ] because this figure better characterizes the invention.
   - [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 98/00522

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61J1/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 696 448 A (MATERIAL ENGINEERING TECHNOLOGY LABORATORY, INC.) 14 February 1996 see column 4, line 11 - column 6, line 11; figures 1-3,6	1-4,8,9, 11,12
X	WO 85 03432 A (TRAVENOL EUROPEAN RESEARCH AND DEVELOPMENT CENTRE) 15 August 1985 see page 9, line 5 - line 20; figures 1-3	1-4,8,9, 11,12
X	WO 95 16490 A (BAXTER INTERNATIONAL INC.) 22 June 1995 see page 14, line 3 - page 19, line 9; figures 1-4	1-4,12

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 May 1998	22/05/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Baert, F

1

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 39 20 775 A (FRESENIUS AG) 3 January 1991 see column 1, line 11 - line 23 see column 2, line 53 - column 4, line 7; figures -----	1-4, 10-12

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 696448 A	14-02-1996	JP 8052196 A	27-02-1996
		US 5662642 A	02-09-1997
WO 8503432 A	15-08-1985	US 4583971 A	22-04-1986
		AU 580584 B	19-01-1989
		AU 3933085 A	27-08-1985
		CA 1234369 A	22-03-1988
		EP 0172836 A	05-03-1986
		JP 3049262 B	29-07-1991
		JP 61501129 T	12-06-1986
WO 9516490 A	22-06-1995	US 5484406 A	16-01-1996
		AU 7732394 A	03-07-1995
		CA 2154764 A	22-06-1995
		EP 0684857 A	06-12-1995
		JP 2736510 B	02-04-1998
		JP 7194710 A	01-08-1995
DE 3920775 A	03-01-1991	NONE	

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
NO 5804/WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP98/00522	21/01/1998	28/02/1997
International Patent Classification (IPC) or national classification and IPC A61J1/20		
Applicant SOCIETE DES PRODUITS NESTLE S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02/09/1998	21.05.99
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. (+49-89) 2399-0 Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Derrien, Y Telephone No. (+49-89) 2399 2622

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP98/00522

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-12 as originally filed

Claims, No.:

1-14 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 5-7
	No:	Claims 1-4, 8-9, 10-11
Inventive step (IS)	Yes:	Claims 12-14
	No:	Claims 1-11
Industrial applicability (IA)	Yes:	Claims 1-14
	No:	Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Reference is made to the following documents:

D1: **EP-A-0 696 448**
D2: **WO-A-85 03432**
D3: **DE-A-3920775**
D4: **WO-A-95 16490**

Re Item V

1.1 The subject-matter of the apparatus-claim **1** is not new (Article 33(2) PCT).
The document D1 discloses (Fig.3) an apparatus which is suitable for modifying and feeding a liquid nutritional feeding composition. It comprises a chamber (1, named instillator) which is suitable for receiving a beneficial agent. The chamber has an inlet (7) connectable (i.e. suitable for being connected) to a container (11. named medicator) and an outlet (2) connectable to a feeding means. The apparatus comprises also pumping means associated with the chamber. According to column 5 line 53-column 6 line 4, the pumping means are here considered to be the container (11) and the flexible wall of the chamber (1): nutritional feeding composition can be pressed from the container (11) into the chamber (1) and back to the container (11).

It is to be remarked that the chamber (A) in Fig.1 of D3 anticipates also the claimed apparatus. It is in particular fitted with an inlet (11) connectable to a container (B) containing the nutritional feeding composition and with an outlet (4) which could be connected to a feeding means. Both containers (A) and (B) are flexible and are used as pumping means (Column 3 lines 58-68).

1.2 The dependent claims **2-9** concern features which are well known in the art or which are adaptations falling within the scope of customary practice followed by the skilled person, such that these claims do not appear to contain any additional features which are new and involve an inventive step as required by Article 33 PCT, when combined with the subject-matter of any claim to which they refer.

In particular, the additional feature of claim **2** is also known from D1.
For claim **3**: A chamber having an inlet and an outlet simply connectable and provided with a flexible wall capable of being squeezed and released for pumping

is generally known and thus not new: it is anticipated for example by commonly known manual laboratory pumps.
As to claim 4, the chamber (A) of D3 contains medicaments.
Claims **5-7** relate to the obvious selection of particular values of time or of composition.
As to claims **8-9**: Hollow spikes are the usual means to create a fluid path between medical devices (see spike 4 in D1 or spike 55 in Fig.3 of D2).

2. The subject-matter of claims **10** and **11** lacks novelty (Article 33(2) PCT). It is known to use devices as disclosed in D1 for modifying and supplying of liquid nutritional feeding composition (see D1 column 5 line 53 to column 6 line 11).

3.1 In view of the available prior art, the independent method-claim **12** meets the requirements of the PCT in respect of novelty, inventive step and industrial application (Article 33 (2), (3) and (4) PCT) for the following reasons:
The documents D1, D2, D3 and D4 reflecting the prior art show devices wherein a first (intermediate) container containing diluent or instilliator is connected at one end to a second container filled with medicator or drug and at the other end to feeding means (see **D1**: col.5 li.57-col.6 li.11; **D2**: p.9 li.18-20; **D3**: col.3 li.58-col.4 li.7; **D4**: p.14 li.23-29). In use, the flexible wall of the first container is squeezed so that the diluent is pressed into the second container. After the drug has been dissolved or mixed with the diluent, the second container is in turn squeezed so that the resultant solution is transferred back into the first container and flows through the first container into the feeding means.

According to the method proposed by the present invention, the beneficial agent is contained by the first (and not in the second) container and the liquid nutritional feeding composition (i.e. the diluent) is placed in the second container.
This intermediate position of the beneficial agent goes against the usual arrangement taught in all documents cited in the search report and is therefore new and not obvious.

3.2 The dependent claims **13-14** relate to preferred embodiments of the subject-matter of claim 12 and also meet the requirements of Article 33 (2), (3) and (4) PCT.

Re Item VII

1. If the Applicant is aware of a document reflecting the prior art which is described on page 2 lines 9-14, then the document should be identified in the description (Rule 5.1 (a) (ii) PCT).

2. The features of claims **1-14** are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Vis-à-vis the available prior art, it appears that a new independent apparatus-claim directed to the whole system, i.e. to a chamber having an inlet connected to a container containing the nutritional feeding composition and an outlet connected to a feeding means, and combined with the additional features of claim 3 (one flexible wall capable of being squeezed and released for pumping) or those of claim 4 (the chamber comprising at least one beneficial agent...) would have met the requirements of the PCT in respect of novelty and inventive step.
With such a claim, any objection concerning the clarity of claims 9 and 12 would be obsolete. At present, claims 9 and 12 are unclear (Article 6 PCT), because no feeding means is explicitly defined in claim 1 (the chamber is only connectable to a feeding means).

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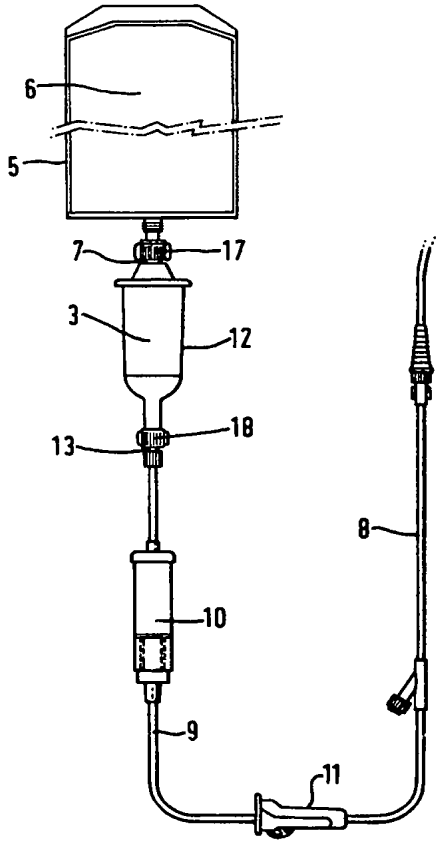
(54) Title: MODIFYING AND SUPPLYING LIQUID NUTRITIONAL FEEDING

(57) Abstract

The present invention relates to an apparatus for modifying and feeding a liquid nutritional feeding composition. Said apparatus comprises 1) chamber 5) for receiving a beneficial agent for modifying a liquid nutritional feeding composition, the chamber having an inlet (7) connectable to a container (5) containing the nutritional feeding composition and an outlet (13) connectable to a feeding means (8, 9) and a pumping means associated (3) with the chamber for pumping said nutritional feeding composition from the container into the chamber and back to the container for mixing the beneficial agent into the nutritional feeding composition before connecting the outlet (13) of said chamber to the feeding means (8, 9). It is preferred that the chamber (3) comprises at least one flexible wall capable of being squeezed and released for pumping of the nutritional feeding composition. The invention also relates to a method for modifying and feeding a liquid nutritional feeding composition.



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MODIFYING AND SUPPLYING LIQUID NUTRITIONAL FEEDING

The present invention relates to an apparatus and method for modifying and feeding a liquid nutritional feeding composition, in particular to its modification by adding a beneficial agent to the liquid feeding composition, before feeding said liquid feeding composition.

It is known to enterally or intravenously feed liquid nutrition to patients who are not able to eat by themselves. Such liquid meals are normally provided in hangable containers such as bottles or plastic bags and are fed from the containers through a tube to the patient. A number of different liquid nutritional feeds are available for the variation of the nutritional intake of the patient. Nevertheless, there is a need for a tailoring of the liquid meals to the patient's individual needs. This is known to be done by adding beneficial agents such as for example nutrients, probiotics and medicaments to the liquid nutritional feed. The adding of such beneficial agents should, for some applications, preferably take place just before the feeding starts as a premature mixing of the liquid nutritional feed and the beneficial agent may considerably increase the quality and shelf-life of the liquid nutritional feed.

The liquid meals provided in hangable containers such as bottles or plastic bags are generally aseptically processed or terminally retorted before use. This

increases the shelf life of the liquid meal. For providing an aseptic feed to the patient, the container is connected directly via a feeding tube or line to the patient. Any opening of the system for adding a beneficial agent increases the risk for bacterial growth or contamination. A closed-line system for the modifying and feeding of patients is therefore desirable.

The prior art discloses closed-line systems wherein a liquid nutritional feeding composition is passing through a chamber comprising a beneficial agent to the patient feeding line. The beneficial agent is mixed or dissolved in the liquid nutritional feeding composition when it is passing through the chamber.

In order to homogenise the feed to the patient in this type of feeding system and thus prevent an over concentration of the beneficial agent, it is necessary to control the release of the beneficial agent. Consequently, a beneficial agent in controlled release form is used, i.e. an agent the solubility of which is delayed or retarded. For example the supplying of the liquid nutritional feed releases the beneficial agent over a period of 2 to 24 hours. Furthermore, although the controlled release form allows the beneficial agent to be released over a period, in-homogeneity may be experienced in the start-up phase due to the protective coating on the beneficial agents.

It is an object of the invention to provide an improved system for modifying and feeding a homogeneous mixture of a liquid nutritional feed and a beneficial agent. In particular to provide a delivery useable for the beneficial agent in a non-controlled release form.

It is a further object of the invention to provide a closed-line system for modifying and feeding a mixture of a liquid nutritional feed composition and a beneficial agent allowing the operations to take place without opening the system to bacteria or contamination.

Accordingly, in a first aspect, the invention concerns an apparatus for modifying and feeding a liquid nutritional feeding composition comprising,

a chamber for receiving a beneficial agent for modifying a liquid nutritional feeding composition, the chamber having an inlet connectable to a container containing the nutritional feeding composition and an outlet connectable to a feeding means, and

a pumping means associated with the chamber for pumping the nutritional feeding composition from the container into the chamber and back to the container for mixing the beneficial agent into the nutritional feeding composition.

Thus, the present invention provides an apparatus for modifying and feeding a liquid nutritional feeding composition which allows the addition of a beneficial agent to the liquid feed immediately before the feeding

commences, which addition of the beneficial agent is done without an opening and reclosing of the system. The mixing of the beneficial agent to the liquid feeding is conducted by pumping means arranged to pump liquid feed from the container into the chamber and liquid and beneficial agent back into the container. After end mixing, the chamber is connected to feeding means for feeding of the mixture to the patient.

It has been found that a homogeneous modification and feeding can be obtained with the feeding system according to the invention. Furthermore, it has been found that the mixture of liquid feed and the beneficial agent is stable during 48 hours' feeding.

In a particularly advantageous embodiment of the invention the pumping means is adapted to vary the volume of the chamber being used for pumping of the nutritional feeding composition. Especially preferred is an embodiment of the invention wherein the chamber comprises at least one flexible wall capable of being squeezed and released for pumping of the nutritional feeding composition. For example, the wall of plastic material the flexibility of which allows a deformation of the wall.

For the embodiment of the above-mentioned flexible wall type, in order to obtain an appropriate pumping effect and thus limit the number of pumping cycles necessary for the mixing of the beneficial agent with the liquid,

the chamber should not be too full of the beneficial agent. Conveniently, at least 30% of the volume of the chamber is empty in the un-squeezed state. Preferably, the volume of beneficial agent constitutes from 5% to 70%, preferably from 30% to 50% of the volume of the chamber. The limits of the ratio filled and un-filled volume will depend on the solubility of the product.

The liquid nutritional feeding composition is of a conventional type. The liquid nutritional feeding composition may comprise from 0 to 25% protein, from 0 to 50% lipids, and from 0 to 60% carbohydrates. For example, it comprises about 15% protein, about 35% lipids, and about 50% carbohydrates. The water content is preferably from 70 to 95% by weight.

The chamber may be delivered as a sealed unit comprising the beneficial agent. Alternatively, the chamber may be filled with the beneficial agent at the location where the treatment is to take place.

The connections between the container, the chamber, and the feeding means are preferably as follows: the inlet is provided with a hollow spike for piercing of a port of the container and creating a fluid path for the nutritional feeding composition. The feeding means comprises a hollow spike for piercing the outlet of the chamber and creating a fluid path for the nutritional feeding composition with the beneficial agent. The piercing of the outlet of the chamber is done after end

mixing. The present system of connection allows for an on-line feeding of an aseptic liquid nutritional feeding composition with a beneficial agent.

The flow of the container to and through the feeding tube means may be due to gravity alone, but preferably the flow from the container to and through the feeding tube means is assisted by a pump.

The beneficial agent is dispersible in the nutritional liquid feed. By dispersible is understood, soluble as well as agents that are suspendable so as to be mixed with the liquid feed and forwarded herewith.

The beneficial agent or agents is/are e.g. selected from the group consisting of nutrients, probiotics, medicaments and diagnostic tracer or a physiological combination thereof.

It is preferred that the or each beneficial agent is dispersible in the nutritional feeding composition in less than 1 min, more preferably in less than 30 sec.

For beneficial agents that are stable in liquid conditions, the agents may be provided in liquid form. Even if the beneficial agent is stable in a certain liquid formulation, a mixture of the liquid nutritional feeding composition and the liquid beneficial agent may not be stable for a longer period, thus the apparatus according to the invention may advantageously be used.

For enteral feeding the beneficial agents are cleaned but there is no need for a sterile product. However, for intravenously fed liquid, the beneficial agent must be sterilised.

The beneficial agent preferably comprises nutrients selected from the group consisting of glutamine, vitamins, arginine, fermentable and non-fermentable dietary fibres, enzymes, oligo elements, combinations of amino acids, oligosaccharides, short chain fatty acids, salts, structured lipids, d-cyroinositol, lactoferrin, marine oils and acidulents, antioxidants or a combination thereof.

The apparatus according to the invention may advantageously be used for enteral or intravenous feeding. For intravenous feeding the beneficial agent is sterilised.

In a second aspect, the invention relates to a method for modifying and feeding a liquid nutritional feeding composition comprising,

connecting a chamber, of the kind described above, to a container comprising a liquid nutritional feeding composition,

pumping liquid feeding composition into the chamber, and liquid nutritional feeding composition and the beneficial agent back to the container to mix with the nutritional feeding composition,

connecting the feeding means, and

allowing the modified nutritional feeding composition to flow through the chamber into the feeding means.

The present invention will now be described in further detail by way of examples only with reference to the accompanying drawings and examples, in which

Fig. 1 is a principle drawing illustrating enteral feeding of a patient with an apparatus according to the invention,

Fig.2 is a cross-sectional principle drawing of the chamber for receiving a beneficial agent, and

Fig. 3 shows a measure of levels of beneficial agent in a feed.

Fig. 1 shows an apparatus 1 according to the invention arranged for modifying and feeding a liquid nutritional feed 6 to a patient, not shown in the drawings. The apparatus 1 comprises a chamber 3 containing a beneficial agent. The chamber 3 is connected to a container 5 containing the nutritional feeding composition 6 via an inlet 7. An outlet 13 in the chamber 3 is connected to feeding tubes 8 and 9 which serve to lead the modified feeding composition to the patient. The feeding tube 9 extends through the nasal path and to the stomach of the patient. Pumping means is provided in the form of the chamber 3 which has a flexible wall structure 12 for pumping the liquid feeding composition 6 into the chamber 3 and back to the

container 5 so as to modify the liquid feeding composition 6. In order to assure attachment between the parts 5, 7, 8, 9 and 13, conventional fastening means 17 and 18 are provided. Furthermore, a pump 10 to assist the flow from the outlet 13 and flow regulation means 11 are provided.

Fig. 2 illustrates a chamber 3 according to the invention. The chamber 3 comprises an inlet 7 and an outlet 13. A chamber wall 12 is provided in a flexible plastic e.g. soft Polycinyl Chloride and a rigid lid 14 is made from a harder plastic e.g. hard Polycinyl Chloride. In the present embodiment the inlet 7 is defined in the lid 14. The lid 14 may e.g. be sealed onto the wall 12 by ultrasonic welding or provided with threads and screwed 4 onto the wall 12.

Before use, the chamber 3 the inlet 7 and the outlet 13 are closed by thin membranes 15 and 16. For the initial mixing of a beneficial agent with a liquid feeding composition, the inlet's membrane 15 is first pierced when being connected to the container 5 shown in Fig. 1. Upon end pumping and mixing, the tube feeding 8 of Fig. 1 is to be connected to the chamber 3 which results in a piercing of the outlet's membrane 16.

EXAMPLE 1

Several liquid nutritional feeding compositions are modified and fed by

1) connecting containers of liquid, feeding to a flexible chamber according to the invention, by piercing the port in the container with the spike of the container,

2) pumping liquid from the container to the chamber and back again by squeezing and releasing the chamber 3 to 5 times, and

3) connecting the feeding means by piercing the outlet of the chamber, thus feeding the modified liquid feed composition to the feeding means. The flow is by gravity or assisted by a pump.

Tests are for example carried out feeding

1) 12 g glutamine as beneficial agent constituting about 60% of the volume of the chamber with 500 ml or 1 L liquid feed.

2) 1 g pro-biotic as beneficial agent constituting about 5% of the volume of the chamber with 500 ml or 1 L liquid feed.

3) 12 g glutamine mixed with 1 g pro-biotic as beneficial agent constituting in total about 65% of the volume of the chamber with 500 ml or 1 L liquid feed.

The liquid feeds are commercially available products such as Réabilan HN, Réabilan, Sondalis ISO, and Sondalis HP supplied by Nestlé S.A. Switzerland.

The modified feed is inspected and characterised as homogeneous.

EXAMPLE 2 - Stability

The stability of the mixture of the liquid nutritional feeding composition and the beneficial agent are controlled by the level of beneficial agent is measured by means of a calorimetric method (Kit Boehringer).

Mixtures of liquid nutritional feeding composition and beneficial agent are fed and samples are stored e.g. 24 hours and 48 hours and the level of beneficial agent is measured.

For example, the stability of Sondalis ISO and Réabilan HN comprising Glutamine are measured over a period:

	Sondalis ISO	Réabilan HN
T= 0h	12,9 g/l	14,6 g/l
T= 24h	12.6 g/l	13,5 g/l
T= 48h	12.5 g/l	12,9 g/l

The measurements show that the Glutamine is stable above a level of 12 g/l after 48 hours.

EXAMPLE 3 - Homogenisation

A homogeneity of the modified liquid nutritional feeding composition is controlled by mixing the beneficial agent

or agents with the liquid nutritional feeding composition by pumping 5 times the liquid into and out of the chamber.

The feeding tube or line is connected to the chamber and an enteral pump running at 100 ml/h, corresponding to a continuous nutrition (24h/42h).

During the feeding, after each 50 ml fed, the level of beneficial agent is measured by means of a calorimetric method (Kit Boehringer).

Fig. 3 shows the amount of beneficial agent in a feed, in the example in question the beneficial agent is Glutamine in a 500 ml in 4 different liquid feeding composition. It is apparent from the figure that the Glutamine level is homogeneously about 12-14 g/l during the feeding period.

EXAMPLE 4

In order to verify that the geometry of the liquid containing container did not influence the homogenisation of the modified feed, trials are conducted with drip-pack, plastic pouches, and glass bottles. No difference in the homogeneity was detected from the various containers.

CLAIMS

1. An apparatus for modifying and feeding a liquid nutritional feeding composition comprising,

a chamber for receiving a beneficial agent for modifying a liquid nutritional feeding composition, the chamber having an inlet connectable to a container containing the nutritional feeding composition and an outlet connectable to a feeding means, and

a pumping means associated with the chamber for pumping said nutritional feeding composition from the container into the chamber and back to the container for mixing the beneficial agent into the nutritional feeding composition.

2. An apparatus according to claim 1, wherein the volume of the chamber being alterable for pumping of the nutritional feeding composition.

3. An apparatus according to either claim 1 or 2, wherein the chamber comprises at least one flexible wall capable of being squeezed and released for pumping of the nutritional feeding composition.

4. An apparatus according to any of claims 1 to 3, wherein the chamber comprises at least one beneficial agent selected from the group consisting of nutrients, probiotics, medicaments (and diagnostic agents) or a (physiological) combination thereof.

5. An apparatus according to any of claims 1 to 4, wherein the or each beneficial agent is dispersible in the nutritional feeding composition in less than 1 min.

6. An apparatus according to any of claims 1 to 4, wherein the or each beneficial agent is dispersible in the nutritional feeding composition in less than 30 sec.

7. An apparatus according to any of claims 4 to 6, wherein the volume of beneficial agent constitutes from 30% to 50% of the volume of the chamber.

8. An apparatus according to any of claims 1 to 7, wherein the inlet is provided with a hollow spike for piercing of a port of the container and creating a fluid path for the nutritional feeding composition.

9. An apparatus according to any of claims 1 to 8, wherein the feeding means comprises a hollow spike for piercing the outlet of the chamber and creating a fluid path for the nutritional feeding composition with the beneficial agent.

10. Use of an apparatus according to any of claims 1 to 9 for modifying and enterally supplying of liquid nutritional feeding composition.

11. Use of an apparatus according to any of claims 1 to 9 for modifying and intravenous supplying of liquid nutritional feeding composition.

12. A method for modifying and feeding a liquid nutritional feeding composition comprising,

connecting a chamber according to any of claims 1 to 2 to a container comprising a liquid nutritional feeding composition,

pumping liquid feeding composition into the chamber and liquid nutritional feeding composition and beneficial agent back to the container to mix the nutritional feeding composition,

connecting the feeding means according to either claims 1 or 9, and

allowing the modified nutritional feeding composition to flow through the chamber into the feeding means.

13. A method according to claim 12, wherein the flow from the container to and through the feeding tube means, is due to gravity.

14. A method according to claim 12, wherein the flow from the container to and through the feeding tube means, is assisted by a pump.

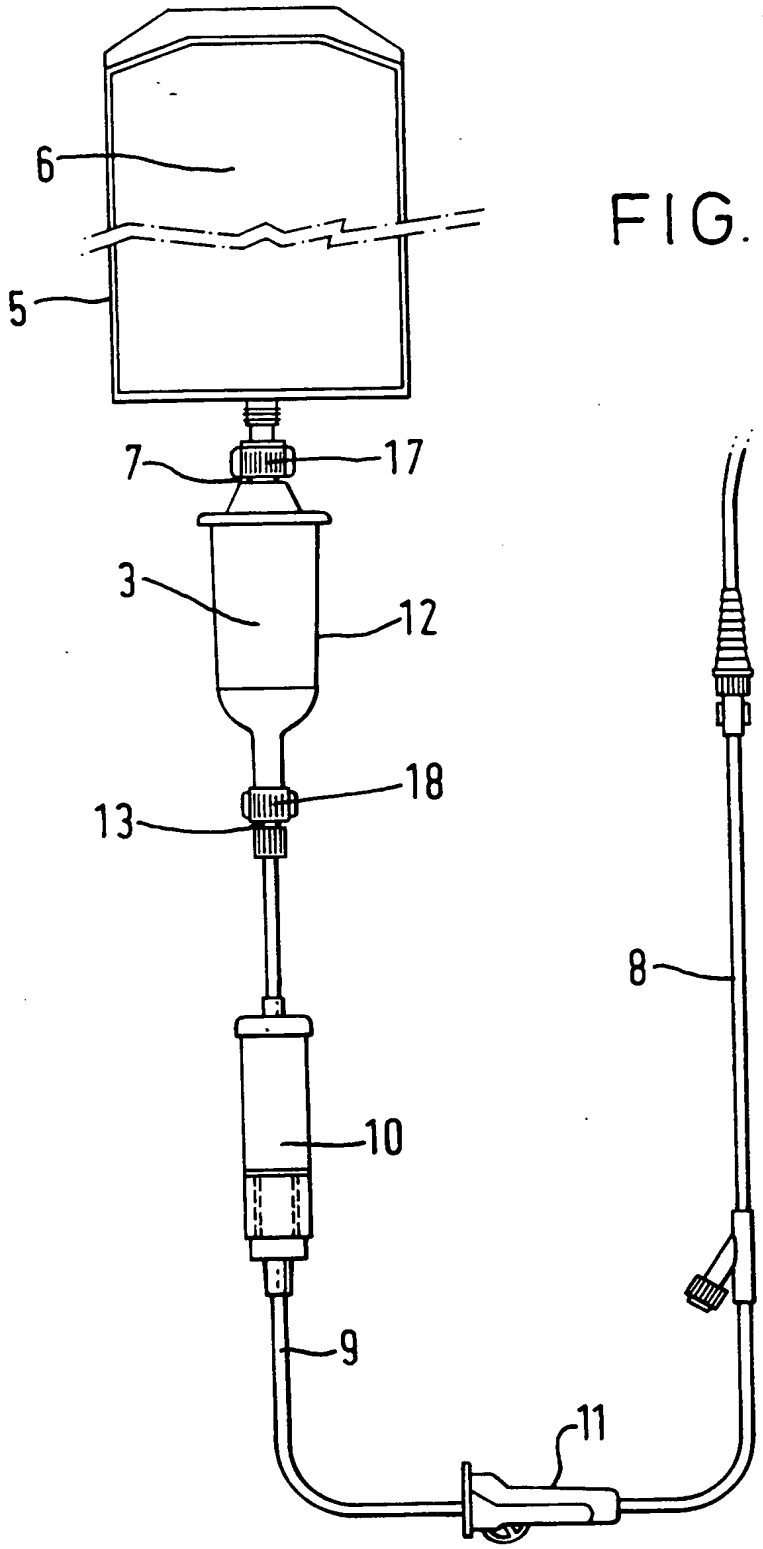


FIG. 1.

FIG. 2.

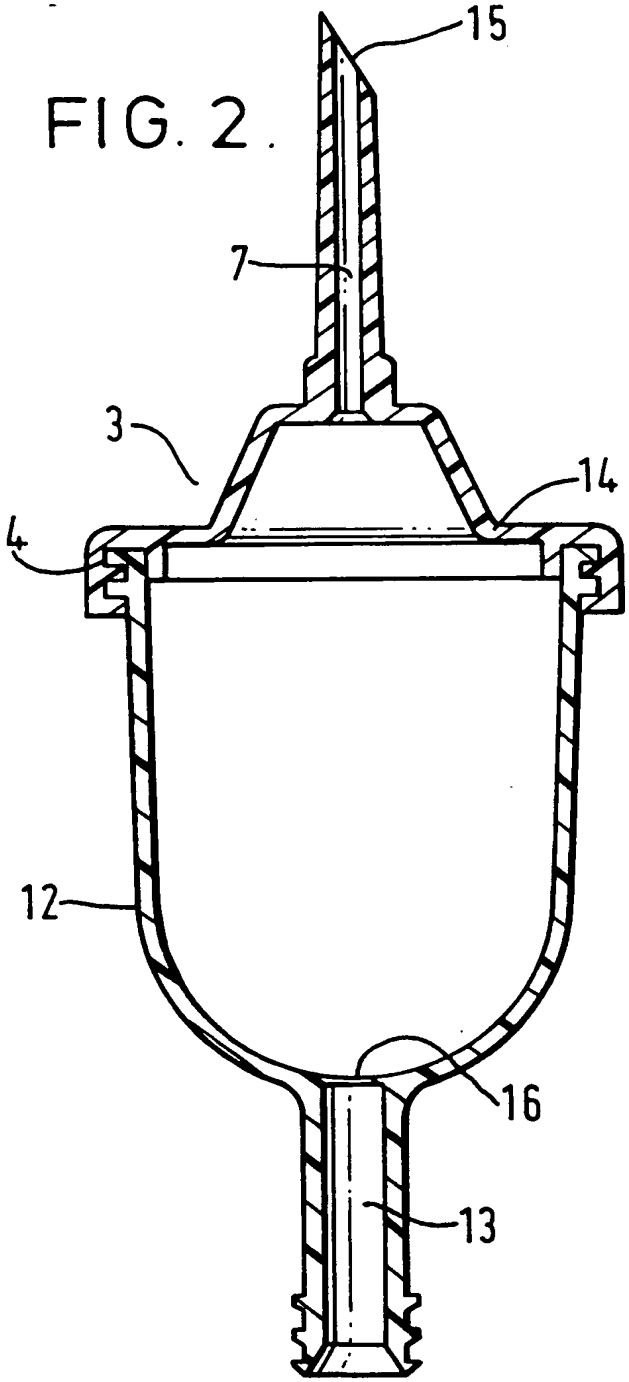
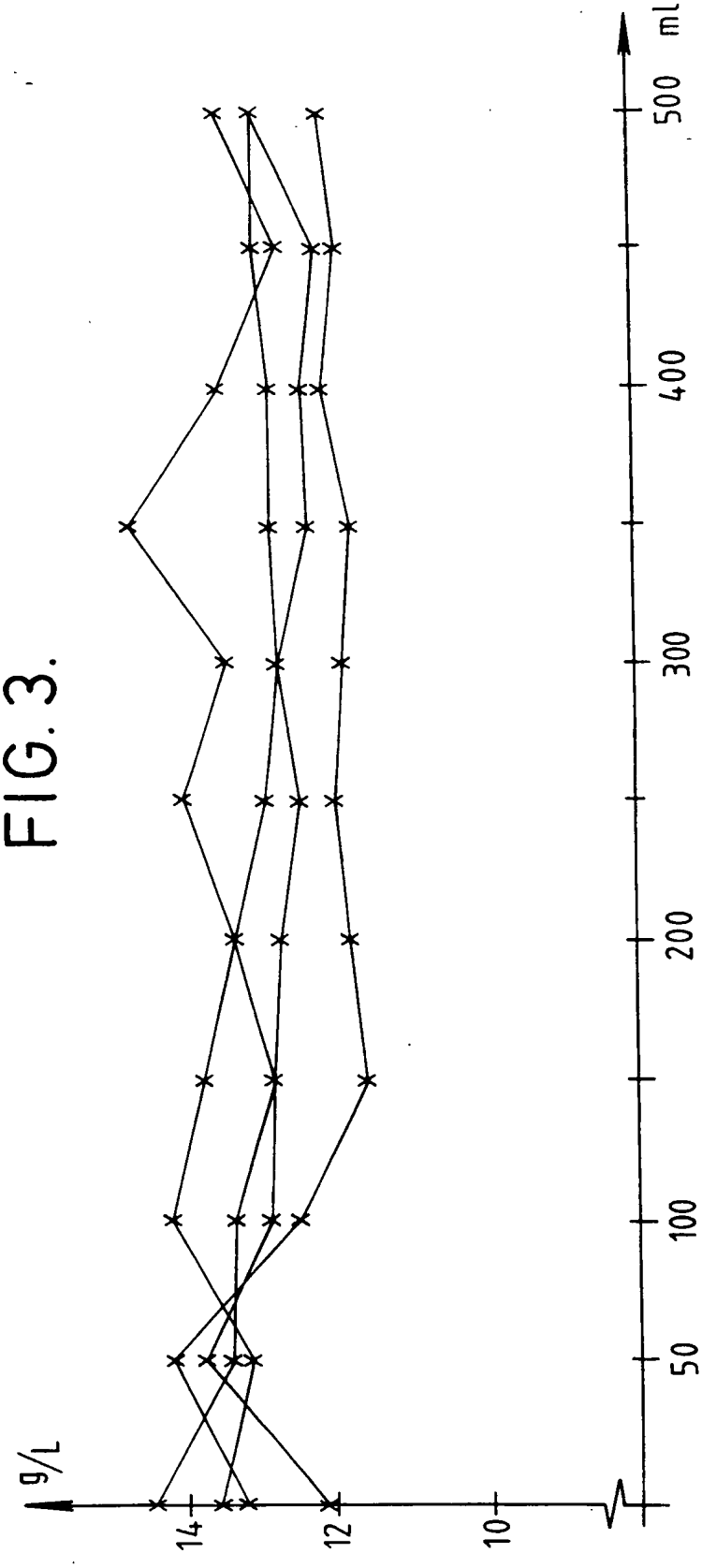


FIG. 3.



INTERNATIONAL SEARCH REPORT

Int. tional Application No
PCT/EP 98/00522

A. CLASSIFICATION OF SUBJECT MATTER
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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 696 448 A (MATERIAL ENGINEERING TECHNOLOGY LABORATORY, INC.) 14 February 1996 see column 4, line 11 - column 6, line 11; figures 1-3,6	1-4,8,9, 11,12
X	WO 85 03432 A (TRAVENOL EUROPEAN RESEARCH AND DEVELOPMENT CENTRE) 15 August 1985 see page 9, line 5 - line 20; figures 1-3	1-4,8,9, 11,12
X	WO 95 16490 A (BAXTER INTERNATIONAL INC.) 22 June 1995 see page 14, line 3 - page 19, line 9; figures 1-4	1-4,12

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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